IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH and BOEHRINGER INGELHEIM CORPORATION,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
ALKEM LABORATORIES LTD., and ASCEND LABORATORIES, LLC,	)	
Defendants.	)	

COMPLAINT

Plaintiffs, Boehringer Ingelheim Pharmaceuticals Inc.; Boehringer Ingelheim International GmbH; and Boehringer Ingelheim Corporation, by their undersigned attorneys, for their Complaint against Defendants, Alkem Laboratories Ltd., and Ascend Laboratories, LLC hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendants' submissions of Abbreviated New Drug Applications ("ANDAs") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of Plaintiffs' JARDIANCE® (empagliflozin) tablets and/or GLYXAMBI® (empagliflozin/linagliptin) tablets prior to the expiration of United States Patent Nos. 8,551,957, 9,949,998, and/or 7,713,938.

THE PARTIES

2. Plaintiff Boehringer Ingelheim Pharmaceuticals Inc. ("BIPI") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Rd., Ridgefield, CT 06877.

3. Plaintiff Boehringer Ingelheim International GmbH ("BII") is a private limited liability company organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

4. Plaintiff Boehringer Ingelheim Corporation ("BIC") is a corporation organized and existing under the laws of Nevada, having a principal place of business at 900 Ridgebury Road, Ridgefield, CT, 06877.

5. BIPI, BII, and BIC are collectively referred to hereinafter as "Boehringer" or "Plaintiffs."

6. On information and belief, Defendant Alkem Laboratories Ltd. ("Alkem Labs") is a corporation organized and existing under the laws of India, having a principal place of business at Senapati Bapat Road, Lower Parel, Mumbai, India 400013.

7. On information and belief, Alkem Labs controls and directs a wholly owned subsidiary in the United States named Ascend Laboratories, LLC ("Ascend Labs"). Ascend Labs is a New Jersey limited liability company having a principal place of business at 339 Jefferson Road, Parsippany, New Jersey 07054.

8. On information and belief, Ascend Labs is acting as the U.S. agent of Alkem Labs with respect to ANDA Nos. 212382 and 212366.

9. Alkem Laboratories Ltd. and Ascend Labs are collectively referred to as "Alkem."

10. On information and belief, Alkem Labs is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs, including distributing, selling, and marketing generic drugs throughout the United States, including within the state of Delaware, through its own actions and through the actions of its agents and subsidiaries, including Ascend Labs, from which Alkem Labs derives a substantial portion of its revenue.

11. On information and belief, Alkem Labs acted in concert with Ascend Labs to prepare and submit ANDA No. 212382 (the "Alkem empagliflozin ANDA") for Alkem Labs' 10 mg and 25 mg empagliflozin tablets and ANDA No. 212366 (the "Alkem empagliflozin/linagliptin ANDA") for Alkem Labs' 10 mg/5 mg and 25 mg/5 mg empagliflozin/linagliptin tablets (the "Alkem ANDA Products"), which was done at the direction of, under the control of, and for the direct benefit of Alkem Labs. Following FDA approval of the Alkem empagliflozin ANDA and the Alkem empagliflozin/linagliptin ANDA, Alkem Labs will manufacture and supply the approved generic product to Ascend Labs, which will then market and sell the product throughout the United States at the direction, under the control, and for the direct benefit of Alkem Labs.

JURISDICTION AND VENUE

12. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, generally, and 35 U.S.C. § 271(e)(2), specifically, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

13. Venue is proper in this Court because, among other things, the defendants are either a foreign corporation not residing in any United States judicial district, or the agent of a foreign corporation. 28 U.S.C. § 1391(c); 28 U.S.C. § 1400(b). Moreover, Alkem has litigated previous Hatch-Waxman patent infringement disputes in the District of Delaware.

14. Ascend has been sued in this district previously, and has not contested personal jurisdiction or venue. *Takeda Pharms. USA, Inc. v. Alkem Labs., Ltd.*, C.A. No. 18-189-RGA (D. Del.).

PERSONAL JURISDICTION OVER ALKEM LABS

15. Plaintiffs reallege paragraphs 1-14 as if fully set forth herein.

16. On information and belief, Alkem Labs develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

17. This Court has personal jurisdiction over Alkem Labs because, *inter alia*, Alkem Labs, on information and belief: (1) has substantial, continuous, and systematic contacts with this State, either directly or through at least one of its wholly-owned subsidiaries or agents; (2) intends to market, sell, and/or distribute Alkem Labs infringing ANDA Products to residents of this State upon approval of ANDA No. 212382 or ANDA No. 212366, either directly or through at least one of its wholly-owned subsidiaries or agents; and (3) enjoys substantial income from sales of its generic pharmaceutical products in this State.

18. On information and belief, Alkem Labs has not contested jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and it has filed counterclaims in such cases. *See, e.g.*, *Takeda Pharms. USA, Inc. v. Alkem Labs., Ltd.*, C.A. No. 18-189-RGA (D. Del.).

19. Alternatively, to the extent the above facts do not establish personal jurisdiction over Alkem Labs, this Court may exercise jurisdiction over Alkem Labs pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Alkem Labs would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Alkem Labs has sufficient contacts with the United States as a whole, including, but not limited to, filing ANDAs with the FDA and manufacturing and selling generic pharmaceutical products that

are distributed throughout the United States, such that this Court's exercise of jurisdiction over Alkem Labs satisfies due process.

PERSONAL JURISDICTION OVER ASCEND LABS

20. Plaintiffs reallege paragraphs 1-19 as if fully set forth herein.

21. On information and belief, Ascend Labs develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

22. This Court has personal jurisdiction over Ascend Labs because, *inter alia*, Ascend Labs, on information and belief: (1) intends to market, sell, or distribute Alkem Labs' ANDA Products to residents of this State; (2) is controlled by Defendant Alkem Labs and is acting as the agent of Alkem Labs with respect to Alkem's ANDAs; (3) makes its generic drug products available in this State; and (4) enjoys substantial income from sales of its generic pharmaceutical products in this State.

23. On information and belief, Ascend has not contested jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs. *See, e.g., Takeda Pharms. USA, Inc. v. Alkem Labs., Ltd.*, C.A. No. 18-189-RGA (D. Del.).

BACKGROUND

U.S. PATENT NO. 8,551,957

24. On October 8, 2013, the USPTO duly and legally issued United States Patent No. 8,551,957 ("the '957 patent") entitled "Pharmaceutical Composition Comprising a Glucopyranosyl-Substituted Benzene Derivate" to inventors Klaus Dugi, Michael Mark, Leo Thomas and Frank Himmelsbach. A true and correct copy of the '957 patent is attached as Exhibit 1. The '957 patent is assigned to BII. BIC and BIPI are licensees of the '957 patent.

U.S. PATENT NO. 9,949,998

25. On April 24, 2018, the USPTO duly and legally issued United States Patent No. 9,949,998 ("the '998 patent") entitled "Pharmaceutical Composition, Methods for Treating and Uses Thereof" to inventors Uli Christian Broedl, Sreeraj Macha, Maximilian von Eynatten, and Hans-Juergen Woerle. A true and correct copy of the '998 patent is attached as Exhibit 2. The '998 patent is assigned to BII. BIC and BIPI are licensees of the '998 patent.

U.S. PATENT NO. 7,713,938

26. On May 11, 2010, the USPTO duly and legally issued United States Patent No. 7,713,938 ("the '938 patent") entitled "Crystalline form of 1-chloro-4-(β-D-glucopyranos-1-yl)-2-[4-((S)-tetrahydrofuran-3-yloxy)-benzyl]-benzene, a method for its preparation and the use thereof for preparing medicaments" to inventors Frank Himmelsbach, Sandra Schmid, Martin Schuehle, Hans-Jürgen Martin, and Matthis Eckhardt. A true and correct copy of the '938 patent is attached as Exhibit 3. The '938 patent is assigned to BII. BIC and BIPI are licensees of the '938 patent.

JARDIANCE®

27. BIPI is the holder of New Drug Application ("NDA") No. 204629 for empagliflozin, for oral use, in 10 mg and 25 mg dosages, which is sold under the trade name JARDIANCE®.

28. JARDIANCE® is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations database ("Orange Book") as having New Chemical Exclusivity until August 1, 2019.

29. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '957, '998, and '938 patents are listed in the Orange Book with respect to JARDIANCE®.

30. The '957, '998, and '938 patents cover the JARDIANCE® product and its use.

GLYXAMBI®

31. BIPI is the holder of New Drug Application ("NDA") No. 206073 for empagliflozin/linagliptin, for oral use, in 10 mg/5 mg and 25 mg/5 mg dosages, which is sold under the trade name GLYXAMBI®.

32. GLYXAMBI® is listed in Orange Book as having New Chemical Exclusivity until August 1, 2019.

33. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '957, '998, and '938 patents are listed in the Orange Book with respect to GLYXAMBI®.

34. The '957, '998, and '938 patents cover the GLYXAMBI® product and its use.

ACTS GIVING RISE TO THIS ACTION

COUNT I — INFRINGEMENT OF THE '957 PATENT

35. Plaintiffs reallege paragraphs 1-34 as if fully set forth herein.

36. On information and belief, Alkem submitted the Alkem empagliflozin ANDA and the Alkem empagliflozin/linagliptin ANDA (collectively, the "Alkem ANDAs") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market the Alkem ANDA Products.

37. Alkem has represented that the Alkem ANDAs refer to and rely upon the JARDIANCE® NDA and the GLYXAMBI® NDA and contain data that, according to Alkem, demonstrate the bioavailability or bioequivalence of the Alkem ANDA Products to JARDIANCE® and GLYXAMBI®.

38. Plaintiffs received letters from Alkem on or about September 24, 2018 stating that Alkem had included certifications in the Alkem ANDAs, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, inter alia, certain claims of the '957, '998, and '938 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Alkem ANDA Products (the "Alkem Paragraph IV Certifications"). Alkem intends to engage in the

commercial manufacture, use, offer for sale, and/or sale of their ANDA Product prior to the expiration of the ’957, ’998, and ’938 patents.

39. Alkem has infringed at least one claim of the ’957 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Alkem ANDAs, by which Alkem seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Alkem ANDA Products prior to the expiration of the ’957 patent.

40. Alkem has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Alkem ANDA Products in the event that the FDA approves the Alkem ANDAs. Accordingly, an actual and immediate controversy exists regarding Alkem infringement of the ’957 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

41. Alkem’s manufacture, use, offer to sell, or sale of the Alkem ANDA Products in the United States or importation of the Alkem ANDA Products into the United States during the term of the ’957 patent would further infringe at least one claim of the ’957 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

42. On information and belief, Alkem’s ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the ’957 patent either literally or under the doctrine of equivalents.

43. On information and belief, the use of Alkem’s ANDA Products constitutes a material part of at least one of the claims of the ’957 patent; Alkem knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the ’957 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not

staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

44. On information and belief, the offering to sell, sale, and/or importation of Alkem's ANDA Products would contributorily infringe at least one of the claims of the '957 patent, either literally or under the doctrine of equivalents.

45. On information and belief, Alkem had knowledge of the '957 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that they will aid and abet another's direct infringement of at least one of the claims of the '957 patent, either literally or under the doctrine of equivalents.

46. On information and belief, the offering to sell, sale, and/or importation of Alkem's ANDA Products by Alkem would actively induce infringement of at least one of the claims of the '957 patent, either literally or under the doctrine of equivalents.

47. Plaintiffs will be substantially and irreparably harmed if Alkem is not enjoined from infringing the '957 patent.

48. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT II — INFRINGEMENT OF THE '998 PATENT

49. Plaintiffs reallege paragraphs 1-48 as if fully set forth herein.

50. Alkem has infringed at least one claim of the '998 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Alkem ANDAs, by which Alkem seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Alkem ANDA Products prior to the expiration of the '998 patent.

51. Alkem has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Alkem ANDA Products in the event that the

FDA approves the Alkem ANDAs. Accordingly, an actual and immediate controversy exists regarding Alkem's infringement of the '998 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

52. Alkem's manufacture, use, offer to sell, or sale of the Alkem ANDA Products in the United States or importation of the Alkem ANDA Products into the United States during the term of the '998 patent would further infringe at least one claim of the '998 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

53. On information and belief, Alkem's ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '998 patent either literally or under the doctrine of equivalents.

54. On information and belief, the use of Alkem's ANDA Products constitutes a material part of at least one of the claims of the '998 patent; Alkem knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '998 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

55. On information and belief, the offering to sell, sale, and/or importation of Alkem's ANDA Products would contributorily infringe at least one of the claims of the '998 patent, either literally or under the doctrine of equivalents.

56. On information and belief, Alkem had knowledge of the '998 patent and, by its promotional activities and package inserts for its ANDA Products, know or should know that they will aid and abet another's direct infringement of at least one of the claims of the '998 patent, either literally or under the doctrine of equivalents.

57. On information and belief, the offering to sell, sale, and/or importation of Alkem's ANDA Products by Alkem would actively induce infringement of at least one of the claims of the '998 patent, either literally or under the doctrine of equivalents.

58. Plaintiffs will be substantially and irreparably harmed if Alkem is not enjoined from infringing the '998 patent.

59. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT III — INFRINGEMENT OF THE '938 PATENT

60. Plaintiffs reallege paragraphs 1-59 as if fully set forth herein.

61. Alkem's Paragraph IV Certifications contained Offers of Confidential Access, offering to provide certain Authorized Evaluators with certain portions of Alkem's ANDAs for the purpose of evaluating whether suit should be brought.

62. Boehringer has requested certain information under the Offers of Confidential Access that it believes necessary to evaluate whether suit should be brought with respect to the '938 patent. To date, Alkem has not provided the requested information. With the 45-day statutory window to commence litigation about to expire, Boehringer is left with no choice but to file the instant action prior to receipt of the additional information requested from Alkem.

63. Alkem has infringed at least one claim of the '938 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Alkem ANDAs, by which Alkem seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Alkem ANDA Products prior to the expiration of the '938 patent.

64. Alkem has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Alkem ANDA Products in the event that the

FDA approves the Alkem ANDAs. Accordingly, an actual and immediate controversy exists regarding Alkem's infringement of the '938 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

65. Alkem's manufacture, use, offer to sell, or sale of the Alkem ANDA Products in the United States or importation of the Alkem ANDA Products into the United States during the term of the '938 patent would further infringe at least one claim of the '938 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

66. On information and belief, Alkem's ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '938 patent either literally or under the doctrine of equivalents.

67. On information and belief, the use of Alkem's ANDA Products constitutes a material part of at least one of the claims of the '938 patent; Alkem knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '938 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

68. On information and belief, the offering to sell, sale, and/or importation of Alkem's ANDA Products would contributorily infringe at least one of the claims of the '938 patent, either literally or under the doctrine of equivalents.

69. On information and belief, Alkem had knowledge of the '938 patent and, by its promotional activities and package inserts for its ANDA Products, know or should know that they will aid and abet another's direct infringement of at least one of the claims of the '938 patent, either literally or under the doctrine of equivalents.

70. On information and belief, the offering to sell, sale, and/or importation of Alkem's ANDA Products by Alkem would actively induce infringement of at least one of the claims of the '938 patent, either literally or under the doctrine of equivalents.

71. Plaintiffs will be substantially and irreparably harmed if Alkem is not enjoined from infringing the '938 patent.

72. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment against Alkem and for the following relief:

a. A Judgment be entered that Alkem has infringed at least one claim of the '957, '998, and '938 patents by submitting the Alkem ANDAs;

b. A Judgment be entered that this case is exceptional, and that Plaintiffs are entitled to their reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

c. That Alkem, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from be preliminarily and permanently enjoined from: (i) engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs or methods of administering drugs claimed in the '957, '998, and/or '938 patents, and (ii) seeking, obtaining or maintaining approval of ANDAs until the expiration of the '957, '998, and/or '938 patents or such other later time as the Court may determine;

d. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Alkem's ANDAs under § 505(j) of the Federal Food, Drug and Cosmetic Act (21

U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '957, '998, and '938 patents, including any extensions;

e. That Boehringer be awarded monetary relief if Alkem commercially uses, offers to sell, or sells its respective proposed generic versions of JARDIANCE®, GLYXAMBI® or any other product that infringes or induces or contributes to the infringement of the '957, '998, and/or '938 patents, within the United States, prior to the expiration of those patents, including any extensions, and that any such monetary relief be awarded to Boehringer with prejudgment interest;

f. Costs and expenses in this action; and

g. Such other and further relief as the Court deems just and appropriate.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)
Brian P. Egan (#6227)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
began@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

Leora Ben-Ami
Jeanna M. Wacker
Christopher T. Jagoe
Mira A. Mulvaney
Sam Kwon
Ashley Ross
Justin Bova
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4679

November 2, 2018